510K(k) SUMMARY

SUBMITTER:	**Gambro Renal Products** **10810 West Collins Avenue** **Lakewood, CO 80215** **(303) 231-5075**
DATE PREPARED:	**June 20th 2006**
DEVICE NAME:	**Gambro Posiclear Filter**
CLASSIFICATION NAMES:	**Water Purification Subsystem**
PREDICATE DEVICE:	**MINNTECH CORP. FIBERFLOW HOLLOW FIBER CAPSULE WATER FILTER**

JAN - 4 2007

Device Description:

The Gambro Posiclear filter consists of a encapsulated, micro porous pleated nylon membrane in a polypropylene housing designed to filter endotoxins, bacteria and particulates from water intended to be used for hemodialysis

Predicate Device:

MINNTECH CORP. FIBERFLOW HOLLOW FIBER CAPSULE WATER FILTER

Intended Use:

The Gambro Posiclear filter is intended to remove bacteria, endotoxin, and particulate matter from water used for hemodialysis. It is intended for use in dialysis water treatment systems as a final stage of filtration after RO or DI treatment to help control bacteria and endotoxin levels in purified water distribution systems. This filter is not intended as a primary means of water purification for hemodialysis

Technological Characteristics:

Comparing the proposed devices to the predicate devices, they are substantially equivalent to the predicate devices. Both the proposed and predicate devices use the a micro porous membrane to remove endotoxin, bacteria and particulates from water intended for hemodialysis.

Summary of Non-Clinical Tests:

In vitro performance testing was performed to establish and compare performance characteristics to the predicate devices.

Conclusions:

Testing performed on the Gambro Posiclear filters indicates that they are safe, effective, and perform as well as the predicate devices, when used in accordance with the instructions for use. In vitro performance data / specifications are included in the labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JAN 04 2007

Jeffrey R. Shideman, Ph.D.
Director, Therapy Group Americas
Gambro Corporate Research
7307 Glouchester Drive
EDINA MN 55435

Re: K061782
Trade/Device Name: Gambro Posiclear
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: June 10, 2006
Received: October 19, 2006

Dear Dr. Shideman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061782

Device Name: Gambro Posiclear

Indications for Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jegura Page __ of ___

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061782

(Posted November 13, 2003)